



# **U.S. Department of Energy's Consolidated Audit Program (DOECAP)**



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**Office of Health, Safety and Security**

**Department of Defense**

**Environmental Monitoring & Data Quality Workshop**

**La Jolla, California**

**March 26-29, 2012**

Report Documentation Page				Form Approved OMB No. 0704-0188	
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1. REPORT DATE <b>MAR 2012</b>		2. REPORT TYPE		3. DATES COVERED <b>00-00-2012 to 00-00-2012</b>	
4. TITLE AND SUBTITLE <b>U.S. Department of Energy's Consolidated Audit Program (DOECAP)</b>				5a. CONTRACT NUMBER	
				5b. GRANT NUMBER	
				5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S)				5d. PROJECT NUMBER	
				5e. TASK NUMBER	
				5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) <b>U.S. Department of Energy, Office of Health, Safety and Security, 1000 Independence Ave. SW, Washington, DC, 20585</b>				8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES)				10. SPONSOR/MONITOR'S ACRONYM(S)	
				11. SPONSOR/MONITOR'S REPORT NUMBER(S)	
12. DISTRIBUTION/AVAILABILITY STATEMENT <b>Approved for public release; distribution unlimited</b>					
13. SUPPLEMENTARY NOTES <b>Presented at the 9th Annual DoD Environmental Monitoring and Data Quality (EDMQ) Workshop Held 26-29 March 2012 in La Jolla, CA.</b>					
14. ABSTRACT					
15. SUBJECT TERMS					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT <b>Same as Report (SAR)</b>	18. NUMBER OF PAGES <b>23</b>	19a. NAME OF RESPONSIBLE PERSON
a. REPORT <b>unclassified</b>	b. ABSTRACT <b>unclassified</b>	c. THIS PAGE <b>unclassified</b>			



# Presentation Outline



- Program Overview
- Audit Checklists and Process
- DoD/DOE Joint Quality Assurance Manual
- Audited Laboratories



# Findings from DOE's Office of the Inspector General and GAO Reports



## Report on the Audit of DOE's Commercial Laboratory Quality Assurance Evaluation Program (June 1995)

- Some laboratories were audited numerous times by a single DOE entity; others were never audited
- Evaluation methods varied significantly from one contractor to another
- Audit results were not shared between contractors

IG and GAO identified that reductions in DOE Auditing of Analytical Laboratory Services was needed



# DOECAP Background



- Purpose of the Program
  - Eliminate/minimize audit redundancies
  - Standardize audit methodology, policies and procedures
  - Communicate Lessons Learned
  - Reduce overall Department risks/liabilities
- Involve all DOE line organizations/field operations
- Auditor participants would be DOE federal employees and contractors



# DOECAP Mission to Improve





# DOECAP Justification



- **Laboratory: DOE Order 414.1, *Quality Assurance***
  - Applies directly to GOCO and commercial laboratories that perform work for the DOE
- **Quality Systems for Analytical Services (QSAS)**
  - Establishes a single, integrated QA program for providers of laboratory services to DOE
  - Based on TNI (NELAC), Chapter 5 (based on ISO 17025) with gray boxes to address DOE specific requirements (radiochemistry, hazardous and radioactive materials management, NDA)
- **TSDF: DOE Order 435.1, *Radioactive Waste Management***
  - Requires that DOE utilize DOE facilities to manage radioactive waste
  - However, if DOE chooses to use a non-DOE waste vendor, DOE must perform an annual qualification audit of the facility



# Results of Formalized DOE Auditing Program



**37 DOECAP Audits/Fiscal Year**

## **FY11 DOECAP Auditing Activities**

### **26 Analytical Environmental Laboratories**

- 22 Commercial
- 4 Government Owned Contractor Operated (GOCO)

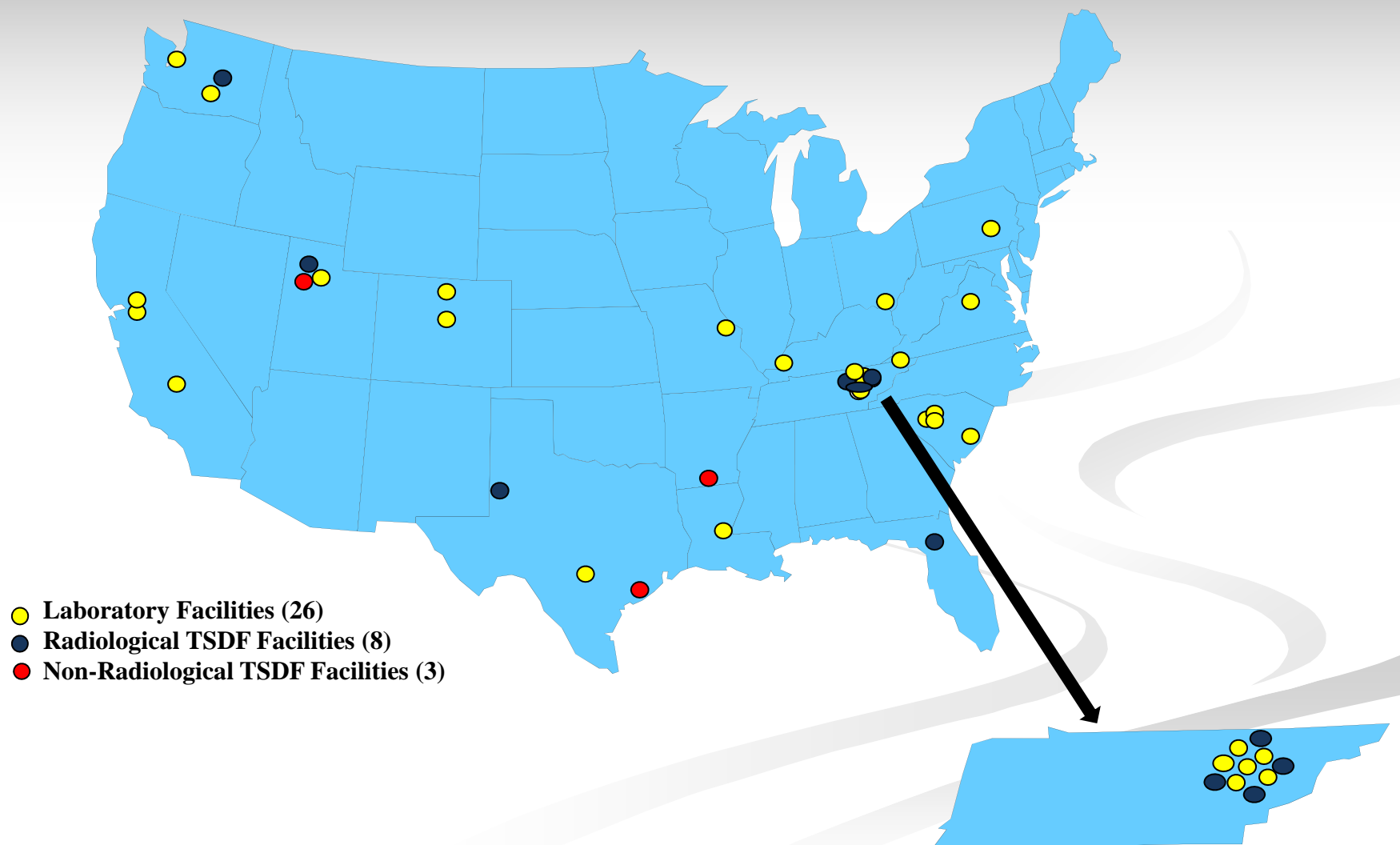
### **11 Treatment, Storage & Disposal Facilities**

- 8 Radiological
- 3 Non-radiological





# FY11 DOECAP Evaluated Laboratories and TSDFs





# Audit Areas



## Laboratory

- Quality Assurance & General Laboratory Practices
- Organic Analysis
- Inorganic Analysis
- Radiochemistry Analysis
- Laboratory Information Management Systems/EDD
- Hazardous and Radioactive Materials Management
- Aquatic Toxicity
- Non-Destructive Assay

## TSDF

- Quality Assurance
- Sampling and Analytical Data Quality
- Waste Operations
- Environmental Compliance/Permitting
- Radiological Control
- Industrial and Chemical Safety
- Transportation Management



# FY 2011 Findings

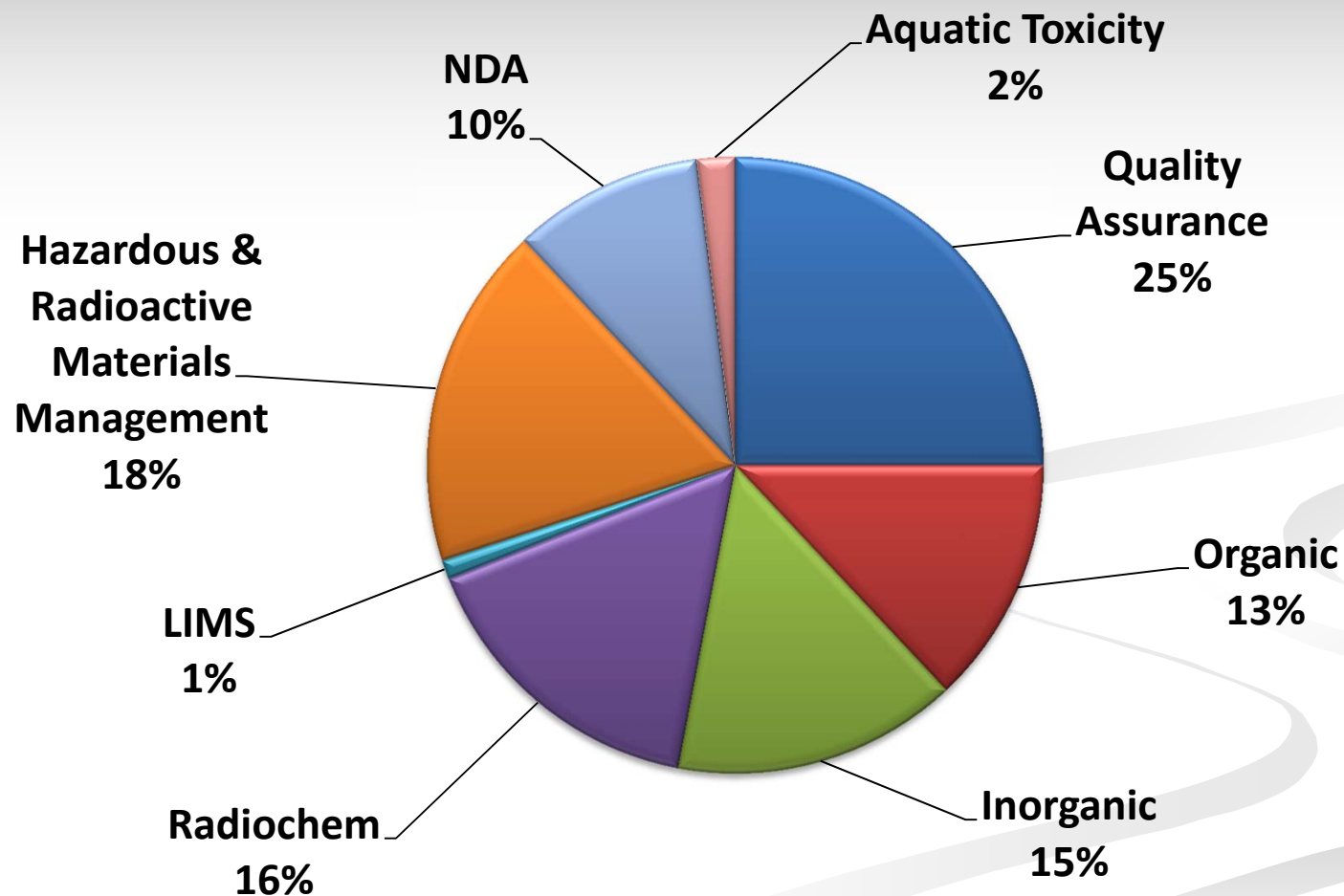


- DOECAP conducted 37 audits in FY2011
- 85% of all FY2010 audit findings were closed during FY2011 audits:
  - 83% of the Lab findings
  - 89% of the TSDF findings
- New Findings Identified Lab & TSDF since 2006:

FY2006 = 269	FY2009 = 277
FY2007 = 374	FY2010 = 227
FY2008 = 216	FY2011 = 215



# Percent Distribution of FY 2011 Lab Findings





# Common Analytical Laboratory Findings



- Inadequate or incomplete SOP content
- Practices do not match SOP direction
- Proficiency Testing failures (unacceptable/warnings results)
- Training not completed or not documented
  - Demonstrations of Capability (Initial & Continuing)
  - Ethics training
  - LIMS security training
  - Safety and Personal Protective Equipment (PPE) training
  - Radiation control training
- Deficiencies in sample receipt practices, particularly radiological screening practices



# Common Analytical Laboratory Findings (cont'd)



- Internal auditing deficiencies
  - None performed
  - Schedule not established or maintained
  - No Corrective Action follow-up
  - Not reported to management
- Calibration or calibration verification deficiencies
- Waste disposal facilities used for waste disposal not adequately evaluated



# DoD/DOE Joint Quality Assurance Manual



## Quality Systems Manual for Analytical Services

### ■ DoD Benefits:

- Expands radiochemistry methodologies
- Sample residual and derived waste disposal, and
- Laboratory worker Environmental Health and Safety practices

### ■ DOE Benefits:

- Expands analytical methods tables

Overall benefit to DoD/DOE is the consolidation of quality and technical requirements



# Laboratory Benefits



- Single approach to satisfy the quality and technical requirements of DoD/DOE
- Reduction in preparation time for laboratory audits
- Single Quality Manual that encompasses the DoD/DOE requirements
- Incorporation of current TNI standard and the requirements of DoD/DOE





# Fy11 Audited Laboratories DoD/DOE Jointly Audited Laboratories



- \*BC Laboratories, Inc., Bakersfield, CA
- \*TestAmerica, Inc., Knoxville, TN
- \*Shealy Environmental Services, Inc., West Columbia, SC
- \*TestAmerica, Inc., St. Louis, MO
- \*GEL Laboratories, LLC, Charleston, SC
- \*TestAmerica, Inc., Arvada, CO
- \*TestAmerica, Inc., Richland, WA
- \*Davis and Floyd, Inc., Greenwood, SC
- \*ALS Laboratory Group, Fort Collins, CO
- \*American Radiation Services, Inc., Port Allen, LA
- \*ALS Laboratory Group, Salt Lake City, UT



# Fy11 Audited Laboratories

## DOE Audited Laboratories



Eberline Analytical Corporation, Oak Ridge, TN

B&W Radioisotope & Analytical Chemistry Laboratory, Lynchburg, VA

B&W Y-12 Analytical Chemistry Organization, Oak Ridge, TN

Radiological Materials Analysis Laboratory,

ORNL UT-Battelle, LLC, Oak Ridge, TN

Portsmouth Analytical Services, Piketon, OH

Caltest Analytical Laboratory, Napa, CA

Paducah Analytical Services, Paducah, KY



## Fy11 Audited Laboratories (cont)



Eberline Analytical Corporation, Richmond, CA

Materials & Chemistry Laboratory, Inc., Oak Ridge, TN

Southwest Research Institute, San Antonio, TX

Lionville Laboratory, Inc., Exton, PA

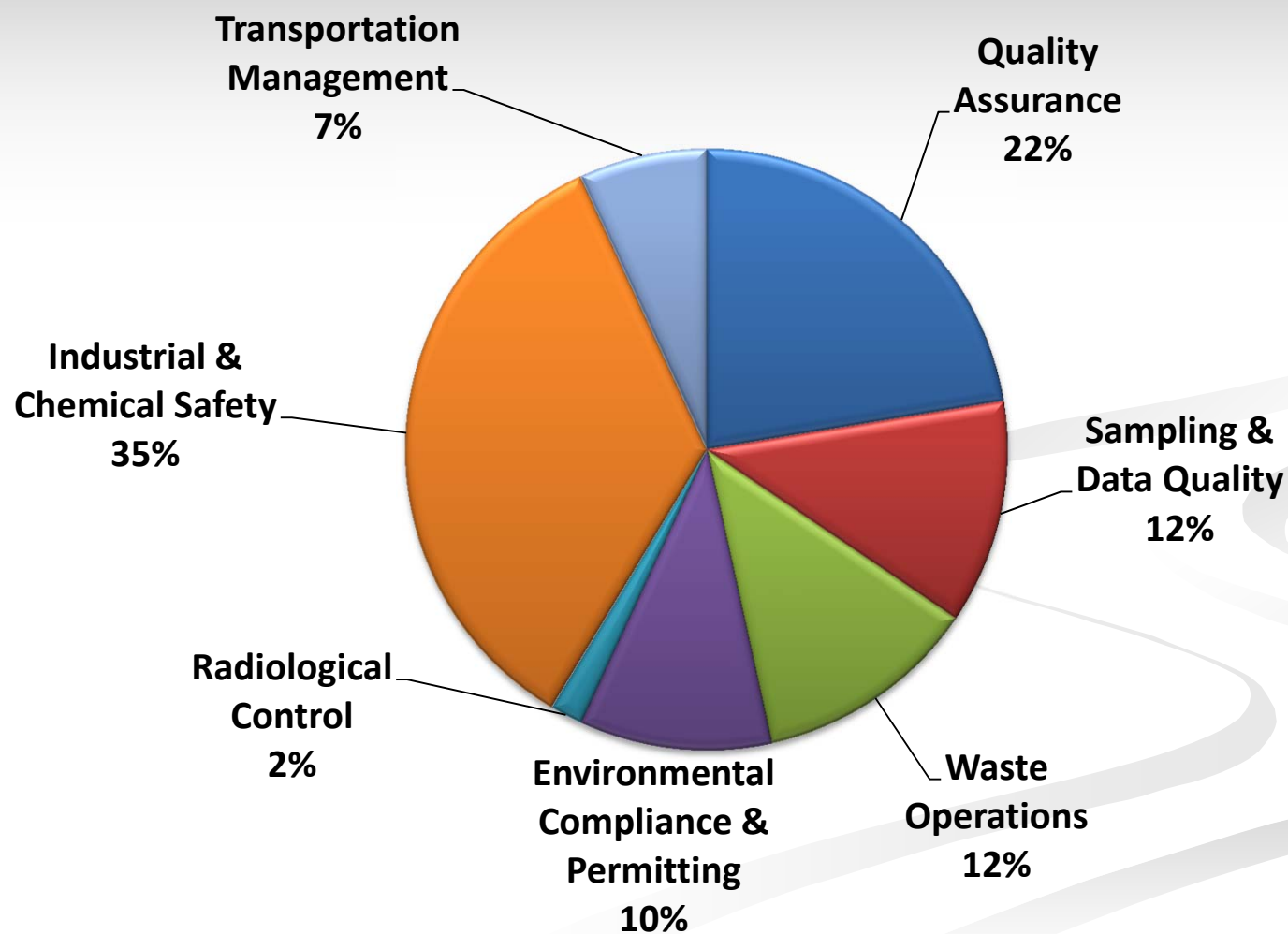
Shealy Consulting, LLC, Lexington, SC

Oak Ridge Institute for Science & Education, Oak Ridge, TN

CEBAM Analytical, Inc., Bothell, WA



# Percent Distribution of FY 2011 TSDF Findings





# Common TSDF Findings



- Incomplete or inadequate SOP content
- Practices do not match SOP direction
- Inadequate personnel training
- Incomplete training documentation and records
- Inadequate labeling and posting (containers, placards, safety, etc.)
- Inappropriate storage of chemicals and equipment
- Inadequate compliance with permits and regulatory requirements



# Laboratory Data Quality Review







# Unlabeled/Unknown Substance Discovered





# DOECAP Program Team



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